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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,262	11/18/2005	Breda Mary Cullen	JJM0618USPCT	9333
27777	7590	09/24/2008	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			KLINKEL, KORTNEY L	
			ART UNIT	PAPER NUMBER
			1615	
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			09/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/528,262	Applicant(s) CULLEN ET AL.	
	Examiner Kortney Klinkel	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 13 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-13 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-13 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/5/2008 and 6/13/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

Receipt is acknowledged of remarks filed June 13, 2008.

Claims 2 and 14-18 were canceled.

Claim 1 was amended

The specification was amended on page 12, line 17 in order to correct the inadvertent typographical error in the cited patent document as per Examiner's request.

Claims 1, 3-13 and 19 are pending in the instant Office Action.

All rejections/objections not addressed herein have been withdrawn.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 3/5/2008 and 6/13/2008 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Response to Arguments

Objection of claims 12 under 37 CFR 1.75, Double Patenting

Applicant's arguments, see page 5, the section titled "the Objection of Claim 12", filed June 13, 2008, with respect to claim 12 being a substantial duplicate of claim 1 have been fully considered. Claim 1 is drawn to a wound dressing composition and

claim 12 by contrast is directed to a wound dressing comprising a wound dressing composition. Because of this fact, Applicant's arguments have been found persuasive.

The objection of March 5, 2008 is withdrawn.

Rejection of claims 1-2 and 5-13 under 35 USC § 103 over Cullen et al. (WO 00/33893)

Applicant's arguments, see page 6, filed June 13, 2008, with respect to the rejection of claims 1-2 and 5-13 under 35 USC § 103(a) as being unpatentable over Cullen et al. (WO 00/33893) have been fully considered but they are not persuasive.

Applicants argue that the Office action dated February 13, 2008 "failed to set forth a *prima facie* basis of obvious[ness] for the claims as presently clarified." Applicants amended claim 1 (and thereby dependent claims 2, now canceled, and 5-13) to recite: the composition "consisting essentially of" the recited components, and argue that this language excludes the therapeutic peptide/polysaccharide complex of Cullen and that this complex does not read on an intimate mixture consisting essentially of a chitosan and an oxidized cellulose. However, the transitional phrase "consisting essentially of" is equivalent to "comprising" (see MPEP 2105). In the absence of a definition of the phrase "consisting essentially of" in the specification, the phrase is read as "comprising". Therefore, the teachings of Cullen still provide a *prima facie* basis of obviousness for the claims as currently amended since Cullen teaches a sterile composition which can be used as a wound dressing including a therapeutic peptide and a polysaccharide selected from the group consisting of oxidized celluloses,

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chitosans and salts and mixtures thereof, as addressed in the Office action dated February 13, 2008.

The transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristics” of the invention. *In re Herz*, 537 F.2d 549, 551-52 (CCPA 1976). Absent a clear indication in the specification or claims of what the basic and novel characteristics of the claimed composition actually are, however, the term “consisting essentially of” is construed as being equivalent in meaning to the term “comprising”. *PPG v. Guardian*, 156 F.3d 1351, 1354 (Fed. Cir. 1998).

For the reasons discussed supra, the rejection is maintained.

Rejection of claims 1, 3-4 and 19 under 35 USC § 103 over Watt et al. (WO 98/00180) in further view of Cullen et al. (WO 00/33893)

Applicant's arguments, see page 7, filed June 13, 2008, with respect to the rejection of claims 1, 3-4 and 19 under 35 USC § 103(a) as being unpatentable over Watt (WO 98/00180) in further view of Cullen et al. (WO 00/33893) have been fully considered but they are not persuasive.

In response to applicant's allegation that there is no suggestion to combine the references, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re*

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Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation for the rejection is found in the references. Cullen teaches that combinations of polysaccharides, including chitosan and oxidized cellulose, can function as wound dressings. Watt teaches the use of oxidized cellulose in the form of dispersed fibers or powders for the treatment of wounds. Because both teachings are for wound dressings comprising oxidized cellulose, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the instant invention to disperse the oxidized cellulose in the form of dispersed fibers or powders.

Applicant's further argue that the teachings of Watt in further view of Cullen fail to teach "an intimate mixture consisting essentially of a chitosan and an oxidized cellulose". For the reasons addressed *supra*, absent a clear indication in the specification or claims of what the basic and novel characteristics of the claimed composition actually are, however, the term "consisting essentially of" is construed as being equivalent in meaning to the term "comprising". *PPG v. Guardian*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). For these reasons, the rejection of claims 1, 3-4 and 19 is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-13 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The application fails to provide support for the phrase: "consisting essentially of a chitosan and an oxidized cellulose". The Examiner carefully studied the specification and the claims and can find no support for this amendment. The language used in the specification, page 4 lines 26-32 states "the present invention preferably comprise an intimate mixture of the chitosan and the oxidized cellulose." The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristics" of the invention. *In re Herz*, 537 F.2d 549, 551-52 (CCPA 1976). The specification is devoid of any clear indication of what the basic and novel characteristics of the claimed composition actually are.

Conclusion

Claims 1, 3-13 and 19 are rejected. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kortney Klinkel, Ph.D. whose telephone number is (571)270-5239. The examiner can normally be reached on Monday-Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached at (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KLK

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615